1. Date and Time: // 20 m m dd yyyy : am pm 24-hour clock
2. Heart Rate/Pulse: /beats per minute
3. Respiratory Rate: /breaths per minute
4. Blood Pressure: / mmHg (systolic/diastolic)

Participant’s/Subject’s Position: Sitting Standing Supine

1. Temperature:○F ○C

Temperature Method:

Oral

Rectal

Axillary

Tympanic

Bladder

Esophageal

Brain

Other, specify:

1. Weight: pounds kilograms
2. Height/Length: inches centimeters

## Additional Pediatric-specific Elements

These elements are recommended for pediatric studies.

1. Head Circumference: inches centimeters

## General Instructions

Vital signs are likely to be captured at study visits to help monitor the health of study participants/subjects and possibly to assess the safety of the intervention.

Height and weight are commonly collected at the baseline visit. Depending on the study population and study intervention it may be appropriate to collect height and weight at subsequent study visits.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Date and time–Record the date vital signs are taken. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database. Not every study will need to collect time and this field should be removed if not applicable.
* Pulse–Record the pulse of the participant/subject in beats per minute.
* Respiratory rate–Record the respiratory rate of the participant/subject in breaths per minute.
* Blood pressure systolic measurement–Record the systolic blood pressure of the participant/ subject. The standard unit for measuring blood pressure is mmHg, which is approximately equivalent to Torr.
* Blood pressure diastolic measurement–Record the diastolic blood pressure of the participant/ subject. The standard unit for measuring blood pressure is mmHg, which is approximately equivalent to Torr.
* Blood pressure position–Record the position the participant/subject was in when blood pressure was measured.
* Temperature–Record the temperature of the participant/subject. Also indicate the scale used to capture temperature.
* Temperature unit of measure-Choose either F (degrees Fahrenheit) or C (degrees Celsius).
* Temperature method–Choose one. Record the location where the temperature was measured. This element is most relevant to pediatric clinical studies.
* Weight–Record the weight of the participant/subject. To be collected at the visit, not self-reported. Also, indicate whether weight was measured in pounds (lbs) or kilograms (kg).
* Weight unit of measure–Choose either pounds (lb) or kilograms (kg).
* Height/Length–Record the height (or length for the very young) of the participant/subject. To be collected at the visit, not self-reported. Also, indicate whether height was measured in inches (in) or centimeters (cm).
* Height/Length unit of measure–Choose either inches (in) or centimeters (cm).
* Head circumference measurement–Record the head circumference of the participant/ subject as well as the units for the measurement.
* Head circumference unit of measure–Choose only one unit.